510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

K042522

B. Purpose for Submission:

Modification to indications for use to include physician's office use

C. Measurand:

Yellowness of skin (bilirubin in the neonate)

D. Type of Test:

Transcutaneous measurements, quantitative readout.

E. Applicant:

Dräger Medical Infant Care Inc.

F. Proprietary and Established Names:

Jaundice Meter JM 103

G. Regulatory Information:

1. Regulation section:

   Bilirubin (total and unbound) in the neonate test system,
   21 CFR 862.1113

2. Classification:

   Class I, reserved

3. Product code:

   75 MQM

4. Panel: 75, Clinical Chemistry

H. Intended Use:

1. Intended use(s):

   See indications for use

2. Indication(s) for use:

   The Jaundice Meter (JM-103) is a non-invasive transcutaneous bilirubinometer. It measures yellowness of subcutaneous tissue in newborn infants. The unit provides a visual digital measurement that has been shown to correlate with serum bilirubin in newborn infants.

   The device is intended for use in hospitals, clinics or doctor's offices under a physicians supervision / direction to assist clinicians in monitoring of newborn infants. The device is not intended as a standalone for diagnosis of hyperbilirubinemia. It is to be used in conjunction with other clinical signs and laboratory measurements.

   Newborn infants whose JM-103 Jaundice Meter test results are indicative of hyperbilirubinemia should be evaluated by their physician(s) for appropriate patient management. Specific neonatal patient Bilirubin levels should be confirmed by other methods, such as serum bilirubin, prior to treatment determinations.

   The JM 103 is a prescription Medical Device
   The JM 103 is not intended for home use.
   The JM 103 may only be used at the sternum measurement site for Physician's office applications.

3. Special conditions for use statement(s):

   The device is not indicated for use during or after exchange transfusions or phototherapy.
   Users are trained by the manufacturer.
   The device is only indicated for sternum measurements in physicians offices. Forehead measurements were not tested in this environment and may be more prone to uncertainties.

4. Special instrument requirements:

   The device includes the instrument. Instrument features of the device are identical to those of the predicate device, and were reviewed previously.

I. Device Description:

The JM-103 Janudice Meter is a handheld meter that measures yellowness of babies skin.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   JM-103 Jaundice Meter

2. Predicate 510(k) number(s):

   K021622

3. Comparison with predicate:

   The device is identical to the predicate device, but the indications have been expanded to include use in physician's offices. This is based on studies performed at physician's office and outpatient clinic sites.

K. Standard/Guidance Document Referenced (if applicable):

L. Test Principle:

The device measures the difference in optical densities for light in the blue (450 nm) and green (550 nm) wavelength regions. The measuring probe is pressed against the sternum of the infant. (Forehead measurements are also indicated for hospital use.) Light from the xenon lamp in the instrument illuminates the skin and is scattered from the subcutaneous tissues to the photodiodes in the instrument. The optical density differences measured are converted to units of mg/dL (estimated or predicted bilirubin) using a clinically determined calibration coefficient . The user can choose a "single measurement mode" or a mode where multiple measurements at one body site can be taken and averaged. A "checker" within the device tests that intensity of light output is within range.

M. Performance Characteristics (if/when applicable):

Performance data in the current submission included method comparison studies at 2 sites: physician's office and outpatient clinic. (Analytical studies, including method comparison and precision at hospital sites were reviewed for the predicate device.)

1. Analytical performance:

   a. Precision/Reproducibility.

Reviewed for K021622 (predicate device).

b. Linearity/assay reportable range:

The device outputs results up to 20 mg/dL estimated bilirubin. See method comparison section below for distribution of results in the method comparison study at physicians office sites.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

The meter contains a "checker" to monitor sufficient light output. The manufacturer recommends that this be used at least once per shift.

It is recommended that users compare JM-103 results to other methods at intervals (such as serum bilirubin, when the physician determines that a serum bilurubin is needed), and record results as an ongoing check of proper operator performance and instrument consistency.

d. Detection limit:

Values as low as approximately 5 mg/dL are included in the method comparison study in this submission.

e. Analytical specificity:

The device measures yellowness of an infants skin. Various factors may affect the bias and variability of the device relative to serum bilirubin. These may include: age of the baby, exposure to sunlight, skin color, user technique, and other factors.

f. Assay cut-off:

Not applicable – this is a quantitative test.

2. Comparison studies:

a. Method comparison with predicate device:

Study Design
Studies compared results obtained with JM-103 to laboratory total serum bilirubin (TSB) methods. Measurements were performed at 2 sites (one doctor's office and one outpatient clinic), by 18 operators, including phlebotomists at the outpatient clinic, and nurses at the doctors office. The study evaluated 201 infants in total. The ages of the infants in the study ranged from approximately 1 day to 7-10 days, with a mean of 3 days (at site 1) and 5 days (at site 2). The number of babies identified as being from

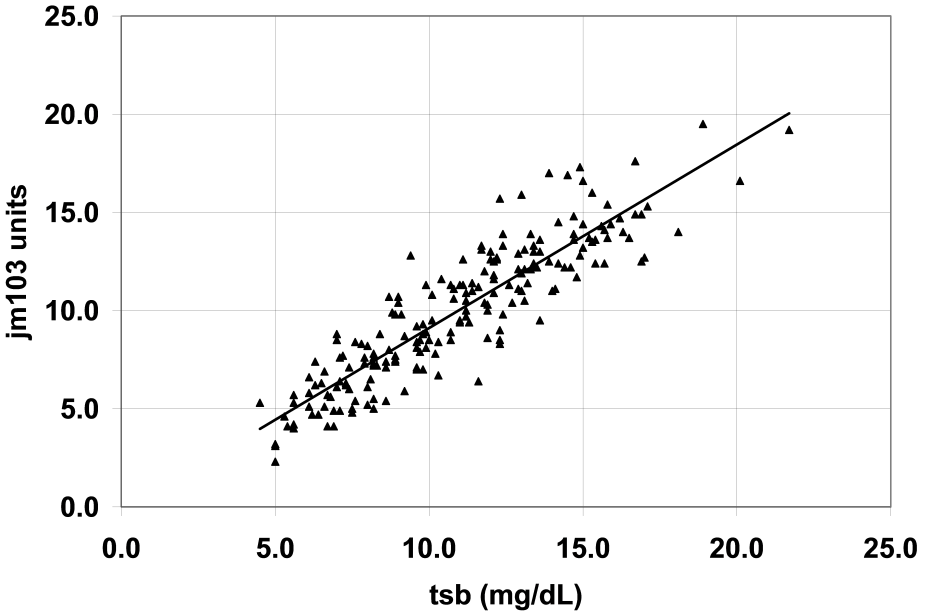
various demographic, or skin color groups are shown below:

	Number
Caucasian	105
African American	13
Mid-Eastern	5
Indian	5
Hispanic	1
Asian	10
unidentified	62

Selection criteria: were infants with indications of jaundice**,** determined by the physician. Exclusion criteria: were infants receiving exchange transfusion or phototherapy.

Results

Combined results of the study are illustrated in the graph below:



Results of regression analysis are shown in the table below for the two outpatient sites. For comparison, the table below also shows results of the analyses for the hospital studies for sternum measurements on Caucasian infants (K021622). The JM-103 results measured at the physician office and outpatient clinic tended to be lower than those reported for the hospital sites, relative to laboratory total serum bilirubin (tsb). This trend appeared to be true for both Caucasian and African American infants.

Site	Slope (95% confidence intervals)	Intercept (95% confidence intervals)	R	SEE (mg/dL)	Patient number (n)
Physician's office - site 1	0.98 (0.89, 1.06)	-0.64 (-1.5, 0.25)	0.90	1.57	133
Outpatient - site 2	0.86 (0.74, 0.97)	0.65 (-0.85, 2.14)	0.88	1.48	68
Hospital site A (K021622) Sternum	1.07	-0.74	0.946	1.02	513
Hospital site B (K021622) sternum	1.16	-0.43	0.89	1.85	100

At the physician's office and outpatient sites, 27% of the JM-103 values were higher than the laboratory total serum bilirubin and 71% were lower. (Two percent were the same).

Of the JM-103 readings falling below the TSB value:
27 measurements (13% of total) were within 2-2.9 mg/dL of the TSB value
12 measurements (6% of total) were within 3-3.9 mg/dL of the TSB value
4 measurements (2% of total) were within 4-4.9 mg/dL of the TSB value

b. Matrix comparison:

Not Applicable

3. Clinical studies:

a. Clinical Sensitivity:

For comparison to serum bilirubin, see method comparison

b. *Clinical specificity:*

For comparison to serum bilirubin, see method comparison.

c. *Other clinical supportive data (when a. and b. are not applicable):*

4. Clinical cut-off:

Each facility should determine their own action levels based on studies of performance of the device on their population. Performance may vary depending on factors such as skin color, age, measurement site and correlation with serum

bilirubin the hands of the user. Careful selection of action levels should be made so that false negatives do not prevent appropriate follow-up measures.

5. Expected values/Reference range:

   See Clinical cutoff, above.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.